REMARKS

Claims 1-20 are pending. By this Amendment, claims 1, 3, 5 and 20 have been amended, and new claims 21-29 have been added. In the Office Action, the Examiner did not provide a basis for rejecting claims 19 and 20, which were added in a previous amendment. Since claims 19 and 20 include elements not presented in the other rejected claims, and since no basis was provided for rejecting these claims, it is submitted that claims 19 and 20 were (and remain) in condition for allowance.

Claim Rejections Under 35 U.S.C. §103

In the Office Action, claims 1-4, 6-9, 12 and 16 were rejected as being unpatentable over Vaitekunas et al. (U.S. Patent No. 5,707,369) in view of Nagai et al. (U.S. Patent No. 5,172,949) AND Stern et al. (U.S. Patent No. 5,443,463) under 35 U.S.C. 103(a). Claims 5, 17 and 18 were rejected as being unpatentable over Vaitekunas, Nagai, and Stern, further in view of Chinn (U.S. Patent No. 5,647,868) under 35 U.S.C. 103(a). Claims 10 and 11 were rejected as being unpatentable over Vaitekunas, Nagai, and Stern, further in view of Hoffman (U.S. Patent No. 4,682,605) under 35 U.S.C. 103(a). Claims 13-15 were rejected as being unpatentable over Vaitekunas and Stern, further in view of Zarudiansky (U.S. Patent No. 4,414,984) under 35 U.S.C. 103(a).

As amended herein, claim 1 recites:

> A system for assessing transmurality of an ablation in a tissue comprising:
>
> an ablation apparatus operatively adapted to deliver ablation energy to a first side of the tissue;
>
> a temperature-sensing pad operatively adapted to sense temperature along a second side of the tissue opposite the first side in response to ablation energy delivered to the first side, the temperature-sensing pad comprising at least one suction opening positioned along a tissue contact surface, the suction opening operatively adapted to anchor the temperature-sensing pad to the tissue;
>
> a suction source in communication with the suction opening, the suction source operatively adapted to provide suction to the suction opening; and
>
> an output device in communication with the pad, the output device operatively adapted to indicate transmurality of the ablated tissue.

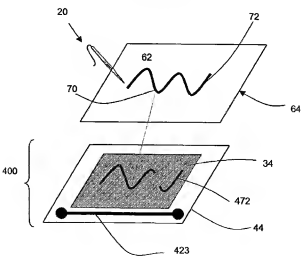
Support for the above amendment is found in paragraphs [0040] and [0043] of the published application (U.S. Published Pat. App. No. 2004/0138656); no new matter has been added by this amendment.

The references cited by the Examiner fail to disclose the elements recited in claim 1. For example, Vaitekunas does not have a temperature-sensing pad, as acknowledged by the Examiner and as required by claim 1. Rather, Vaitekunas teaches a temperature sensor "secured to the outer back surface of the [ablation] element 18." Col. 4, ll. 51-55. Further, the placement of the temperature sensor on the ablation element fails to meet the limitations of claim 1 for the additional reason that the temperature sensor is not adapted to sense temperature changes along a second side of the tissue opposite the first side, as required by claim 1.

As noted in the specification, an example of a problem addressed by certain embodiments of the invention is assessing the transmurality of ablation lesions:

"... even if the ablation process creates a continuously linear line along the top surface of the target tissue, it is not assured that the tissue is continuously and completely ablated through further layers of the target tissue (i.e. it is not assured that transmurality is achieved.) Transmurality is achieved when the full thickness of the target tissue is ablated." Background section, Para. [0007] of Published Pat. App. Ser. No. 2004/0138656. FIG. 5, below, illustrates this problem:

FIG. 5



In the example shown above in FIG. 5, lesion 72 formed on a first tissue surface 62 may result in a representation 472 (e.g., temperature or transmurality) at second tissue surface 64 on the opposite side of the tissue. In the example shown, a dark line representation 472 may indicate locations where sensed temperatures at the second surface 64 are sufficient to cause cell death. Thus, the example illustrates a situation where the lesion is transmural in certain portions (e.g., the dark line portions), and not transmural in certain other portions (e.g., the gray portion between the dark line segments). The lesion illustrated is therefore not "continuous" at the second surface 64.

As noted in the specification, "If the temperature of the surface farthest from device 20 (surface 64) is high enough to achieve cell death, the user may assume that the temperatures of the tissue nearer to device 20 are also high enough to achieve cell death. In such an instance, the user may assume that transmurality has been achieved. As described above, system 10 provides feedback on display 210 regarding the temperature of the surface 64 farthest from device 20 and thereby provides feedback on the transmurality of lesion 72." Specification, Para. [0043].

As noted above, the device of Vaitekunas is not adapted "to sense temperature along a second side of the tissue opposite the first side in response to ablation energy delivered to the first side," as required by claim 1, since the temperature sensor of Vaitekunas is secured to the outer back surface of the ablation element. The arrangement of Vaitekunas is therefore not capable of assessing the transmurality of ablation lesions in the manner claimed in claim 1.

The Stern reference illustrates a "coagulating linear patch" (Stern, FIG. 6), "which may be used to control or stop surface bleeding." Col. 7, ll. 18-19. However, Stern fails to address the failings of Vaitekunas in that the electrodes 330 and temperature sensors 340 of Stern are located on the same surface of the patch in FIG. 6, and therefore are not adapted to sense temperature changes along a second side of the tissue opposite the first side, as required by claim 1.

Nagai teaches a suction pad with temperature control mechanism. However, the Nagai device is concerned with controlling the temperature of the suction pad itself. Nagai states, "In response to the temperature signal from the temperature sensor 18, the temperature control device controls the electric heater 16 to keep the workpiece attracting surface 46 of the suction pad at a temperature suitable for the workpiece to be transferred by the suction pad 10." Col. 3, ll. 20-25. One of ordinary skill in the art would not have been disposed to consider a reference

like Nagai, which is completely unconcerned with the problem of assessing the transmurality of ablated tissue. Further, the combination of Vaitekunas, Stern, and Nagai would not result in the claimed invention, since Nagai does nothing to address the failings of Vaitekunas and Stern noted above. Since the prior art references cited by the Examiner, either alone or in combination, do not disclose the elements of claim 1 as amended, claim 1 is believed to be patentable and in condition for allowance.

Since claims 2-19 all depend from independent claim 1, either directly or indirectly, they are also believed to be patentable for at least the reasons given above with respect to claim 1, and for other reasons as well. Independent claim 20 has been amended to include limitations similar to those found in claim 1 and is believed to be patentable for reasons analogous to those provided with respect to claim 1.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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